

REMARKS

Rejection Under 35 USC 103(a)

Claims 82-87 and 91-100 have been rejected under 35 USC 103(a) as being unpatentable over Mouritsen et al. in view of van der Zee et al. More specifically the Patent Office states:

Mouritsen et al. disclose the attachment of one or more T cell epitopes into the highly conserved self-protein ubiquitin (see pages 6-7). Mouritsen discloses 2 different ubiquitin fusion proteins: one containing the T-cell epitope ovalbumin (OVA325-336) and the other containing the T-cell epitope HEL(50-61). Injection of said fusion proteins into mice elicited a strong antibody response to the fusion protein. Moreover, Mouritsen et al., disclose, "the insertion of one or more foreign T-cell epitopes induces a profound autoantibody response against said proteins" (see page 6, lines 31-33). Finally, Mouritsen discloses, "the antibody response induced was not necessarily restricted to the inserted T cell epitopes" (see page 6, lines 33-35). van der Zee et al., teach a fusion protein comprising GnRH fused to fimbriae for the development of a contraceptive vaccine for use in domestic animals."

This rejection is respectfully traversed. Applicants' invention differs profoundly from the combined teachings of Mouritsen et al. and van der Zee et al. Mouritsen et al. teach the use of ubiquitin in a fusion protein as a self epitope, whereas Applicants teach the use of ubiquitin in a fusion protein as a T-cell epitope. Mouritsen et al. does not teach the ability of ubiquitin to generate an immune response as a T-cell epitope in a protein fusion. Mouritsen et al. instead teach the ability of HEL(50-61) and OVA(325-336) to generate an immune response as T-cell epitopes in protein fusions. Mouritsen et al. teach that said T-cell epitopes HEL(50-61) and OVA(325-336) generate an immune response not necessarily restricted to the inserted T cell epitopes. While Mouritsen et al. disclose that antibodies generated in an immune response by an OVA(325-336)-ubiquitin or HEL(50-61)-ubiquitin fusion protein are directed not only to the OVA and HEL epitopes, but also to the ubiquitin self epitope, one of skill in the art could not say with any degree of certainty that said immune response could be due to ubiquitin. van der Zee et al. teaches use of the highly immunogenic carrier P-fimbriae fused to a short, non-immunogenic GnRH decapeptide to generate an immune response to the GnRH decapeptide in an animal. While van der Zee et al. teaches use of GnRH as a self epitope, van der Zee et al. does not teach the use of ubiquitin for generating an immune response to GnRH. The ability of ubiquitin to

generate an immune response to a self epitope in a fusion protein was not previously appreciated in the art, and the discovery of said ability by Applicants was an unexpected result.

Rejection Under 35 USC 112, Second Paragraph

Claims 91-94 have been rejected under 35 USC 112, second paragraph. This rejection has been obviated by the claim amendments set forth above.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,



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